

REMARKS/ARGUMENTS

A petition for a two-month extension of time is filed herewith.

Examiner has maintained the rejections of claims 1-22 and 24-35 are rejected under 35 U.S.C. 103, as being unpatentable over Lai in view of Nochumson, Monestere, and Rudnick is maintained.

Examiner has further maintained the provisional rejection of claims 1, 7-8, 13, 15, 19 and 21 as being unpatentable over claims 9 and 23-24 of copending application 10/715,745 is maintained.

Examiner has noted that reactivity ratios are not disclosed in Table 2. Examiner is correct. Reactivity ratios are listed in Table 4, on page 34. The reactivity ratios in Table 4 are calculated using the data points in Table 2. The data in Table 4 clearly shows that both the intensity and initiator concentrations impact reactivity ratio, and that the recited ratios provide the recited silver uptake.

The Examiner has rejected claims 1-22 and 24-35 under 35 U.S.C. 103, as being unpatentable over Lai in view of Nochumson, Monestere, and Rudnick.

The claims of the present application recited processes for incorporating silver into a polymer formed from a reactive mixture comprising at least one ligand monomer. The reactive mixture is cured “under conditions sufficient to provide a reactivity ratio of the ligand monomer to at least one major lens forming component of at least about 0.45”.

Applicants have surprisingly found that the curing under reaction conditions sufficient to provide the recited reactivity ratio is critical to achieving the desired loading of silver in the resulting antimicrobial lens. Examiner has said that Lai et al. inherently discloses the recited reactivity ratios and that the recited reactivity ratios are a matter of “judicious selection”. Applicants respectfully disagree.

Lai et al. neither discloses nor suggests incorporating any of the recited ligand monomers into the reactive mixture. As such, Lai et al. cannot inherently disclose a “reactivity ratio of ligand monomer to at least one major lens forming component” as is currently recited, because there is no ligand monomer present.

Lai et al. does disclose that initiators may be used in amounts from “about 0.1 to 2 percent by weight”. Col. 5, lines 35. However, this is no disclosure or suggestion as to what cure conditions should be used to get the desired reactivity ratio. All of the Examples in Lai et al. use initiator concentrations of 0.2 (well below those shown in Tables 2 and 4 of the present application to be useful), and the intensity of the UV light used for curing is not disclosed.

Table 4, page 34 of the present application clearly shows that both the initiator concentration and cure intensity must be balanced to achieve the recited reactivity ratio and the recited silver concentration. As shown in Table 4, at initiator concentrations below about 1%, even intensities of 6 mW/cm² were insufficient to provide the recited reactivity ratios. Table 2 shows that at these conditions silver concentrations were below the recited 80% of target. The combination of cure conditions necessary to provide the recited reactivity ratios is not disclosed nor inherent in Lai et al.

Monestere and Nochumson are also absolutely silent as to the need to cure reactive mixtures comprising at least one ligand monomer under conditions sufficient to provide the recited reactivity ratios. None of the references cited by Examiner disclose the conditions necessary to calculate or estimate a reactivity ratio, let alone suggest that the reactivity ratio would be important for any reason, let alone for the incorporation of silver after the lens is formed. Applicants have clearly shown that the recited reactivity ratios are critical to achieving efficient silver loading in the recited antimicrobial lenses.

Examiner has further stated that the references taken as a whole reasonably suggest antimicrobial lenses, since they teach incorporation of silver nitrate, which would necessarily render the lenses antimicrobial. This is not correct. Monestere et al. is the only reference of the three which discloses treating a lens with silver nitrate. Monestere et al. discloses exposing the lens to silver nitrate, precipitating silver chloride in the lens, and then reducing the silver chloride to metallic silver (“the actual opaquing material”). Col. 2, lines 60-63. Monestere et al. further discloses that “the opaquing materials are physiologically inert”. Col. 5, lines 5-6. Monestere et al, therefore discloses that the lenses are physiologically inert, not antimicrobial as is recited in the present claims.

Examiner has further stated that

“curing the lens to where the ratio of ligand monomer (N,N’-bisacylylcystamine) to one major lens forming component is merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. For example, Lai et al. teach adding crosslinking agents, i.e. N,N’-bisacylylcystamine in a range of 0.01 to about 10 wt% and curing the monomeric mixture with polymerization initiators, where the initiators are at a concentration of about 0.001 to 2 percent. (See col.5, lines 22-24, and lines 26-35.) The artisan could add the crosslinking agent at 0.1% and add the initiator at 0.22%, which would yield a ratio of about 0.45.”

The reactivity ratio recited in the claims is the ratio of the *reactivity* of the ligand monomer to the *reactivity* of at least one lens forming monomer in the reactive mixture at a given set of reaction conditions. The reactivity, r , is calculated as described on page 33, lines 5-13 using the following equations:

$$\text{The reactivity } r_{\text{component}} = 1/\tau_{\text{component}}$$

$$[\text{component}](t) = \text{Res} + A \exp(-t / \tau)$$

where

$[\text{component}](t)$ is the concentration of the component as a function of exposure time t ,
 Res is the concentration of residual (unreacted) component after the reaction is exhausted,
 $A(=1-\text{Res})$ is the normalized initial concentration, and
 τ is the exponential decay constant.

The 0.45 ratio calculated by Examiner above, appears to be a ratio of initial starting concentrations of the crosslinker and initiator. This is not the reactivity ratio recited in the present claims. A simple ratio of starting concentrations discloses nothing of the relative reactivities of the components, as is recited in the present claims. Lai et al., Nomansen and Monestere et al. fail to disclose exposure time (t), concentration of the reactive components as a function of exposure time ($[\text{component}](t)$) or the concentration of residual (unreacted) component after the reaction is exhausted (Res). None of the variables necessary to calculate the reactivities of the components are disclosed in those references.

The reactivity ratios in Table 4 clearly show that initiator concentration alone does not insure the desired reactivity ratio. Since Lai et al. and Monestere are silent as to specific initiator concentration/cure intensities, those lens would not inherently incorporate the desired amounts of silver.

The Examiner further maintained the provisional rejections of claims 1, 7-8, 13, 15, 19 and 21 as being unpatentable over claims 9 and 23-24 of copending application 10/715,745 and 10/719,903.

As discussed above, concentrations of components at different times in the reaction must be measured to calculate reactivities. The information needed to make such calculations is not disclosed in either copending application. Moreover, there is nothing in either application which would suggest that a specific ratio of reactivities would be desired. Instead, the applications disclose that the initial concentration of ligand is important. Applicants have found, in the present application that controlling the starting application is not enough, the reactivities must also be controlled to provide the recited ratio. This is not suggested by either copending application.

Applicants respectfully submit that the foregoing arguments have traversed the Examiner's rejections. Withdrawal of the rejection, and allowance of the claims is requested.

If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (904) 443-3074.

Respectfully submitted,

Date: January 6, 2009

/Karen A. Harding/
Karen A. Harding
Registration No. 33,967

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(904) 443-3074